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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,377	11/15/2001	Carlo Gambacorti-Passerini	45922/241203 (5865-2)	4010

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,377	GAMBACORTI-PASSERINI ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. While it appears that Applicant is in compliance with the Sequence Rules, Applicant is required to review the instant application for compliance with the requirements of applications which contain sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825. If the instant application does not have an appropriate SEQ ID NO: for each disclosed sequence, then Applicant must comply with the Sequence Rules as set forth in 37 CFR 1.821-1.825.

2. Prior to setting forth the restriction requirement, it is noted that the claims are drawn to patentably distinct methods and products. The methods of treating a disorder with an ALK peptide either A) by itself, B) bound to an antigen presenting cell, C) with a T lymphocyte specific for said peptide in a complex with HLA-A*0201, or D) with a functional variant, differ in structure and modes of action to such an extent and have non-coextensive searches of such an extent that they are considered separately patentable. It is noted that in claim 12 the phrase "functional variant thereof" lacks antecedent basis in the claims. The scope or metes and bounds of claim 12 are also unclear, as "functional variant thereof" may refer to peptides, antigen presenting cells or T cells. For restriction purposes, functional variant has been interpreted to be a distinct group that if elected, will be subjected to further restriction to define the nature of the "functional variant". Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3 and 4, drawn to an ALK peptide, pharmaceutical composition, and vaccine, classified in Class 530 subclass 328, and Class 424, subclass 185.1.

II. Claim 2, drawn to an antibody that binds an ALK peptide, classified in Class 530, subclass 388.85.

III. Claims 5-8, drawn to a method of inducing a cytotoxic response, classified in Class 435, subclass 7.24.

IV. Claims 9 and 10, drawn to an antigen presenting cell carrying an ALK peptide, classified in Class 435, subclass 372.

V. Claim 11, drawn to a T lymphocyte that binds an HLA class I molecule and an ALK peptide, classified in Class 435, subclass 372.3.

VI. Claims 12-15, drawn to a method for treating a disorder using an ALK peptide, classified in Class 514, subclass 2.

VII. Claims 12-15, drawn to a method for treating a disorder using an antigen presenting cell that carries an ALK peptide, classified in Class 424, subclass 93.7

VIII. Claims 12-15, drawn to a method for treating a disorder using an autologous T lymphocyte specific for an ALK peptide in a complex with HLA-A*0201, classified in Class 424, subclass 93.71.

IX. Claims 12-15, drawn to a method for treating a disorder using a functional variant, classified in Class 424, subclass 184.1.

X. Claims 16-21, drawn to an isolated nucleic acid encoding an ALK peptide, a vector and host cell for the production of an ALK peptide, classified in Class 536, subclass 23.5 and Class 435, subclasses 320.1 and 325.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions (I/IV/V and III), (I and VI-VIII), (IV and VII), and (V and VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the peptides and peptide containing compositions of Group I, can be used in the production of antibodies rather than for inducing a cytotoxic response (Group III) or treating a disorder (Groups VI-VIII). The antigen presenting cells and T lymphocytes of Groups IV and V, respectively, can be used as *in vitro* tools for studying cytokine responses to ALK expressing tumors rather than in a cytotoxicity assay (Group III) or methods of treating a disorder (Groups VII and VIII).

5. Inventions I, II, IV, V, and X are different products.

Peptides, antibodies, vaccines, antigen presenting cells, T cells, nucleic acids, vectors and host cells are distinct because their structures and modes of action are distinct.

6. Inventions III and VI-IX are different methods.

These inventions require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.

7. Inventions ((II/X) and (III and VI-VII)), (IV and VI/VIII), (V and VI/VII) and (I/II/IV/V/X and IX) are not related as products and method of use.

Therefore, they are patentably distinct.

8. Because these inventions are distinct for the reasons given above and the literature searches required for Groups I-X are divergent and Groups I-X have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct species of the claimed invention relating to ALK peptides in Groups I-X. The species are as follows:

A) SEQ ID NO: 1,

B) SEQ ID NO: 2,

C) SEQ ID NO: 3,

D) SEQ ID NO: 4,

E) SEQ ID NO: 5,

F) SEQ ID NO: 6, or

G) SEQ ID NO: 7.

These species are distinct because they differ in structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 2, 4, 5, 9, 11, 12, and 16 are generic for example.

10. This application also contains claims directed to the following patentably distinct species of the claimed invention relating to a method of inducing a cytotoxic response and treating a disorder, Groups III and VI-IX, respectively. The species are as follows:

A) an ALK-positive lymphoma,

B) neuroblastoma, or

C) an ALK expressing neoplasia.

These species are distinct because they have different etiologies, characteristic cellular populations, therapeutic interventions and endpoints.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 5 and 12 are generic for example.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CRF 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus,

to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 30, 2004

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